

REMARKS

The present amendments to the specification are made to add the priority information.

Applicant notes that the Office Action states that the preliminary amendment dated March 31, 2006 has not been entered. Accordingly, Claims 1-88 are canceled herein without prejudice to, or disclaimer of, the subject matter contained therein. Applicant maintains that the cancellation of a claim makes no admission as to its patentability and reserve the right to pursue the subject matter of the canceled claim in this or any other patent application.

New Claims 89-105 are added herein. The new claims are supported by the claims and specification as originally filed. In particular, support for the new claims can be found, for example, at paragraphs [0010]-[0012], [0018], [0021], [0022], and [0027]-[0029] of the specification. Accordingly, no new matter is added by the amendments to the claims.

Upon entry of the amendments, Claims 89-105 are presented for examination.

Applicant responds below to the objections and rejections made by the Examiner in the Office Action of February 10, 2009.

Discussion of Rejection Under 35 U.S.C. § 112, First Paragraph - Enablement

The claims have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that the specification does not enable methods of medical treatment and compositions for medical treatment containing tetrameric oxygen.

Without acquiescing in the rejection, and solely to expedite prosecution, Applicant has canceled all claims specifying methods of medical treatment and compositions for medical treatment containing tetrameric oxygen. Applicant has herein submitted new claims herein directed to methods of increasing oxygen levels in a tissue or methods of treating a medical condition using a composition that “comprises between about 10% and about 25% free available oxygen by volume.” It is well accepted in the PTO that 35 U.S.C. §112 does not require that an Applicant describe the theory of operation of an invention, but rather, that the Applicant need only describe the invention and enable its practice. The PTO had taken issue with the stated theory of operation of the formulation disclosed herein – tetrameric oxygen – so the present claims instead recite the physical properties of the material as set forth in the specification.

Because the Examiner's rejection is directed to the recited theory of operation; i.e., tetrameric oxygen, the Examiner's rejections are inapplicable to the claim set as amended. Applicant submits that the claimed methods are fully enabled by the specification.

In addition, Applicant provides herewith a Declaration under 37 C.F.R. §1.132 by Dr. Judith Boston (Exhibit 1). Dr. Boston is an expert in the field of the claimed subject matter. See *Boston Declaration* at ¶2 and Exhibit A. The Boston Declaration provides objective *in vitro* and *in vivo* evidence that the compositions disclosed in the present specification (referred to as primary oxygenating ingredient (POI) in the Boston Declaration) comprising elevated free available oxygen by volume can: 1) protect cells from hypoxic conditions and 2) improve visual function in ischemic rabbit eyes.

The declaration demonstrates that POI protected human retinal pigment epithelial cells when grown under hypoxic cell culture conditions. See *Boston Declaration* at ¶¶6-7.

Vascular endothelial growth factor (VEGF) is a protein that can stimulate neovascularization, which can be induced by hypoxia and which occurs in many disorders, such as ophthalmic retinopathies. See, e.g., *Specification* at ¶[0027]). Exhibit B, annexed to the Boston Declaration, shows that VEGF expression increased in human retinal pigment epithelial cells when the cells were grown under hypoxic culture conditions and that POI normalized hypoxia-induced increases in VEGF expression when cells were grown under hypoxic conditions in the presence of POI. See *Boston Declaration* at ¶¶8-9 and Exhibit B.

Furthermore, Exhibit C, annexed to the Boston Declaration, provides evidence that POI was able to significantly preserve and/or restore B wave function (a measure of the output signal of the retina to incident light) in ischemic rabbit eyes *in vivo*. See *Boston Declaration* at ¶¶10-11 and Exhibit C.

The results provided in the declaration demonstrate that, regardless of the mechanism of action, compositions of the claimed methods can inhibit or reverse phenotypes normally associated with hypoxia in both *in vitro* and *in vivo* experiments.

In view of the amendments to the claims and the evidence of operability and positive physiological effect of the claimed methods presented herein, Applicant submits that the claimed methods are fully enabled by the specification. Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

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No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of the above amendments and remarks, Applicant respectfully maintains that the claims are patentable and request that they be passed to issue. If the Examiner has any questions which may be answered by telephone, the Examiner is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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